DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 25, 2014

Boston Scientific Corp.
Ms. Diane Nelson
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K141150
Trade/Device Name: Sterling MR PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 21, 2014
Received: August 25, 2014

Dear Ms. Nelson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141150

Device Name: **Sterling™ Monorail™ Balloon Dilatation Catheter**

Indications for Use:

Sterling™ Monorail™ Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Diane Nelson Regulatory Affairs Specialist Phone: 763-255-0813 Fax: 763-494-2222 e-mail: diane.nelson@bsci.com
Date Prepared	02 May 2014
Proprietary Name	Sterling™ Monorail™ PTA Balloon Dilatation Catheter
Common Name	PTA Balloon Dilatation Catheter
Product Code	LIT – Catheter, Angioplasty, Peripheral, Transluminal
Classification	Class II, 21 CFR Part 870.1250 – Percutaneous Catheter
Predicate Device(s)	Sterling™ Monorail™ PTA Balloon Dilatation Catheter, K053118, cleared 16 December 2005 Sterling™ OTW PTA Balloon Dilatation Catheter, K132430, cleared 17 October 2013 Sterling™ SL Monorail™ and OTW PTA Balloon Dilatation Catheters, K093720, cleared 23 December 2009
Device Description	The Sterling Monorail Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is a high performance balloon catheter for peripheral indications. The device features an ultra low profile, semi-compliant balloon combined with a low profile tip. The catheter is compatible with either 0.014 in (0.36 mm) or 0.018 in (0.46 mm) guidewires. The Sterling Monorail PTA Balloon Dilatation Catheter is a Monorail brand rapid exchange catheter with a semi-compliant balloon fixed at the distal tip. The balloon catheter has a coaxial shaft design. The outer lumen is used for inflation of the balloon, and the wire lumen permits the use of guidewires 0.014 in / 0.018 in (.36 mm / .46 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. Two radiopaque marker bands (one proximal and one distal), in conjunction with fluoroscopy, enable accurate positioning of the balloon. Markers on the 80 cm and 90 cm effective length catheters indicate the exit of the dilatation catheter tip out of the guiding catheter (one at 50 cm and two at 60 cm). Markers on the 135 cm and 150 cm effective length catheters indicate the exit of the dilatation catheter tip out of the guiding catheter (one at 90 cm and two at 100 cm). The effective lengths of the balloon catheter are 80 cm, 90 cm, 135 cm, and 150 cm. A needle with a luer port is included for flushing the distal inner lumen prior to the

	insertion of appropriate guidewires.
Intended Use/ Indications for Use of Device	The Sterling Monorail PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

Comparison of Technological Characteristics

The Sterling Monorail PTA Balloon Dilatation Catheter will incorporate a substantially equivalent design, packaging, fundamental technology, materials, manufacturing, sterilization and intended use as those featured in the predicate BSC Sterling Monorail and OTW Balloon Dilatation Catheters.

Comparison to Predicate Device in Materials and Manufacturing

Characteristic	Comparison to Predicates
Manifold	Same material and design serving the same function.
Manifold Bond Adhesive	Same material and design serving the same function.
Corewire	Same material and design serving the same function.
Outer Shaft	Same material and design serving the same function.
Inner Shaft	Same material, colorant and design serving the same function.
Balloon	Same material and design serving the same function and fundamental technology.
Markerbands	Same component serving the same function.
Proximal Marks	Same material and design serving the same function.
Coating	Same coating serving the same function.
Bumper Tip	Same material, colorant and design serving the same function.
Sterilization Method	Same method.
SAL	Same level of assurance.
Balloon Diameters	Additional balloon diameters: 1.5, 2.0, and 2.5mm.
Balloon Lengths	Additional balloon lengths: 100, 150, 200, and 220mm.
Usable Catheter Lengths	Additional catheter lengths: 90 and 150cm.
Rated Burst Pressure (RBP)	Same Rated Burst Pressure.
Recommended Introducer Sheath Compatibility	Sheath compatibility within the predicate compatibility range, same function.
Recommended Guidewire	Same compatibility.
Packaging	Same function and design.

Performance Data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. The Sterling Monorail PTA Balloon Dilatation Catheter met all acceptance criteria for the bench and biocompatibility testing with results similar to the predicate. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The following biocompatibility and bench testing were completed on the Sterling Monorail PTA Balloon Dilatation Catheter:

Biocompatibility

The device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The testing included MEM Elution Cytotoxicity, Hemocompatibility (Direct Contact), Chemical Characterization-USP Physicochemical, and Natural Rubber Latex.

The following leveraged in-vitro performance tests were completed on the Sterling Monorail PTA Balloon Dilatation Catheter:

Bench

Bond Integrity	Balloon Burst Mode
Working Length	Balloon Compliance
Deflation Time	Balloon Nominal Diameter
Balloon Rated Burst Pressure (RBP)	Burst in a Stent
Balloon Multiple Inflation	Balloon Body Length
Crossing Profile	Guidewire Movement
Full Catheter Tensile Extension and Deflation	Sheath Withdrawal
Balloon Multiple Inflation in a Stent	Marker Band to Balloon Alignment
Particulate Evaluation	Torque After Conditioning
Proximal Balloon Bond and Shaft Tensile Strength	

Conclusion

Based on the Indications for Use, technological characteristics, safety and performance testing, the Sterling™ Monorail™ PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Sterling™ Monorail™ PTA Balloon Dilatation Catheter (K021721 cleared 16 December 2005) and the Sterling™ OTW Balloon Dilatation Catheter (K132430 cleared 17 October 2013) and the Sterling™ SL Monorail™ and OTW PTA Balloon Dilatation Catheters (K093720 cleared 23 December 2009).